K123070
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MAR 15 2013

510(k) Summary
for
Sirona Dental Systems
GALILEOS family

1. Sponsor

Sirona Dental Systems GmbH
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D-64625 Bensheim
Germany
Contact Person: Fritz Kolle
Telephone: +49 6251 16 3294
Date Prepared: September 28, 2012

2. Device Name

Proprietary Name:	GALILEOS family
Common/Usual Name:	X-ray, Tomography, Computed, Dental
Classification Name:	Computed tomography x-ray system

3. Predicate Devices

Sirona GALILEOS (K060892), Genoray VOLUX 21C (K120263)

4. Intended Use

Devices of the GALILEOS family consist of an x-ray system that uses a cone beam with a rotational sequence, providing two dimensional images and three dimensional volume reconstructions of the head area, which includes ENT and dentomaxillofacial areas, for use in planning and diagnostic support in adult and pediatric care.

Devices of the GALILEOS family comprise a package of PC software modules to expand SIDEXIS capabilities to handling 3D data. This includes 3D reconstruction, storage, retrieval, viewing and processing of 3D-image data.

5. Device Description and Function

The GALILEOS family is an extraoral source dental X-ray system intended to produce X-rays for obtaining three dimensional volume reconstructions of the teeth, jaw, and the head area, which includes ENT and dentomaxillofacial areas, for use in planning and diagnostic support in adult and pediatric care.
The GALILEOS family device generates a conical x-ray beam that rotates around the patient's head within a certain angle.
The device comprises an image receptor for 3D volume exposure with an adjustable diaphragm. Three volume regions are defined through this. Class I laser beam light localizers serve to position the patient's head that may be fixed through bite block and adjustable forehead and temple supports.

From the obtained exposures a three dimensional image is reconstructed and can be viewed as well as panoramic/cephalometric images. The constructed 3D volume and simulated projection exposures as well as panoramic/cephalometric data are conveyed to SIDEXIS and stored in the SIDEXIS data base.

An operator control panel allows height adjustment, selection of mode and program, and indicates machine states.
A separate handhold push-button serves for exposure release
An optional remote control is available.

6. Scientific Concept

The underlying scientific concept is cone-beam x-ray technology. All volumetric exposures are obtained by cone-beam technology.

7. Physical and Performance Characteristics

7.1. Design

The GALILEOS family comprises of a support stand to which a height adjustable sled is attached. The sled carries the patient fixation, the operator control panel (easy pad) and the motor driven rotatable ring. The X-ray source and image receptor are fixed to the ring. During a scan the device generates a conical x-ray beam that rotates around the patient's head at varying angles.
Class I laser beam light localizers serve for positioning the patient's head that may be fixed through bite block and adjustable forehead and temple supports.

The exposure area is defined by the geometry of the GALILEOS family devices.
A control panel allows the user to select the exposure modes and the exposure factors, view the machine status information, control the height adjustment and turn on the laser indicator.

An optional remote control is available.

The PC software reconstructs the three-dimensional image as well as process panoramic / cephalometric images. The constructed 3D volume and simulated projection exposures as well as panoramic/ cephalometric data are conveyed to SIDEXIS and stored in the SIDEXIS database.

7.2. Material Used

Materials that come into patient contact intentionally are biocompatible and evaluated according to ISO 10993-1: 2003, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

7.3. Physical Properties

Not applicable.

8. Summary of the technological characteristics

The GALILEOS family with the new member GALILEOS Comfort^{PLUS} is a further development of the GALILEOS (K060892).

All members of the GALILEOS family provide adapted programs of the GALILEOS and the same 3D operating principles as the predicate device GALILEOS.

The new member of the GALILEOS family the GALILEOS Comfort^{PLUS} has a different source to skin distance than the GALILEOS and the image intensifier has a new mode to support the increased amount of images during an exposure.

The devices of the GALILEOS family have two type of X-ray generators. The predicate GALILEOS was capable of maximum 85kV with 7mA and the new GALILEOS Comfort^{PLUS} is capable of maximum 98kV with 6 mA.

All GALILEOS family devices now include a mechanical diaphragm.

The PC software performs identical functions and algorithms as the GALILEOS. The software has been adapted to the higher number of images.

The GALILEOS family offers a calculated panoramic view in combination with slices orthogonal to the panoramic curve ('transversal slices') as the predicate GALILEOS. The GALILEOS family offers nearly the same functionality in viewing slices, projections and volume views.

9. Nonclinical Testing

The GALILEOS family system functions have been tested in a system test (covers the requirements from the function specification, the risk/hazard analysis and the functionality of the equipment from the user's perspective).

The exposure programs have been tested utilizing test phantoms. The tests evaluate the equality of exposures of proposed GALILEOS family and predicate device GALILEOS.

Additional tests have been performed taking into account FDA Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, Document issued on: August 6, 1999" adapted for image intensifier products.

10. Clinical Testing

Clinical tests have not been performed.

11. Conclusion

Based on a comparison of intended use, indications, construction materials, principle of operation, features, and technical data, the Sirona Dental GALILEOS family and the new member GALILEOS Comfort^{PLUS} is safe and effective to perform its intended use and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 15, 2013

Mr. Fritz Kolle
Sirona Dental Systems GmbH
Fabrikstrasse 31
BENSHEIM, GM D-64625

Re: K123070
Trade/Device Name: GALILEOS Comfort PLUS
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: February 06, 2013
Received: February 13, 2013

Dear Mr. Kolle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123070

Device Name: GALILEOS Comfort PLUS

Indications for Use:

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Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

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